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Healthcare and care through distance-spanning technologies

Cross-border ePrescriptions and Patient Summaries in the Nordic countries

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Foreword

This report describes the current situation for cross-border ePrescriptions and Patient Summaries in the Nordic countries and on a European level.

The report is the result of the project *Cross-border ePrescriptions and Patient Summaries in the Nordic countries*, part of the Nordic Council priority project *Healthcare and care through distance-spanning technologies (VOPD)*. The project was initiated as part of the Nordic Council of Ministers' Swedish Presidency Programme in 2018.

International Project Coordinator Hans Andersson prepared this report. Carl Jarnling, Head of Unit, is responsible for the assignment.

Head of Department Peter Alvinsson approved the report after a presentation by Carl Jarnling, Head of Unit.

Peter Alvinsson

Head of Department eHealth Services

Stockholm, 24 May 2021

Executive summary

The Nordic Council of Ministers' Vision 2030 aims to make the Nordic Region the most sustainable and integrated region in the world.

The separate Nordic countries are already at the forefront when it comes to the use of ePrescriptions at a national level. It is a good start, but some Nordic countries need to develop their national solutions for ePrescriptions further to manage cross-border ePrescriptions.

The Swedish Presidency of the Nordic Council of Ministers in 2018 implemented a special focus on e-health. The Swedish eHealth Agency was tasked to examine and suggest a plan for continued work on ePrescriptions and Patient Summaries across Nordic national borders. This document is the Final Report on that work.

Of the Nordic countries, Finland and Sweden have decided to implement cross-border ePrescription services. Only Finland has decided to implement cross-border Patient Summaries.

Looking at developments in the rest of Europe, 16 out of 27 EU countries plan to implement both cross-border ePrescription and Patient Summary services by 2023. Also, another two countries plan to introduce ePrescriptions and six are drafting plans for Patient Summaries.

The current status of ePrescriptions and Patient Summaries in the Nordic countries:

Country	ePrescription	Patient Summary
Denmark	Not actively working on ePrescription cross-border services. Is following developments and will reassess participation in the future.	Not actively working on Patient Summary cross-border services. Is following developments and will reassess participation in the future.
Finland (Åland[1])	In January 2019, Finland was the first country to implement a cross-border ePrescription service. Finnish ePrescriptions can, in March 2021, be dispensed in Estonia, Croatia and Portugal. In 2020, Finland launched a service to dispense ePrescriptions from other participating member states in Finland. ePrescriptions from Estonia, Croatia and Portugal can now be dispensed.	The plan is to make Finnish Patient Summaries available in other participating countries by the end of 2023 and open the service for foreign Patient Summaries in Finland by 2024 with national coverage.
Iceland	Not actively working on ePrescription cross-border services.	Not actively working on Patient Summary cross-border services.

[1] In Åland the Finnish implementation of the eP cross-border service is used.

	Awaiting political decisions.	Awaiting political decisions.
Norway	Not actively working on ePrescription cross-border services. A new assessment will be carried out, but it has not yet been decided when this will happen.	Not actively working on Patient Summary cross-border services. A new assessment will be carried out, but it has not yet been decided when this will happen.
Sweden	The ePrescription services will technically be ready to go live in 2021. The cross-border services will be implemented when the legal conditions are in place. The Ministry of Health and Social Affairs has appointed an investigation to submit proposals for national regulation. The work will be reported to the Ministry in September 2021.	In 2020, Sweden analysed the operational, semantic, technical and legal prerequisites for Patient Summaries. The Swedish government has not communicated any more planned work or activities in the area of cross-border Patient Summaries.

Figure 1 Cross-border ePrescriptions and Patient Summaries – current status in the Nordic countries

Conclusion

If its vision of forming an area within the European Union that is at the forefront of e-health, including cross-border services to its citizens, is to be realised, there must be political will at both the Nordic and national level. Decisions to prioritise cross-border ePrescription work need to be made in all of the Nordic countries.

The cross-border ePrescription and Patient Summary projects can function as guiding examples for cross-border health data exchange. It will provide the necessary infrastructure for further services, such as medical imaging, discharge letters, laboratory results, rare diseases and other health data exchanges.

In October 2019, at the 71st session of the Nordic Council, it was unanimously decided (62-0) that the Nordic Council would recommend to the Nordic Council of Ministers that Nordic citizens should be able to retrieve ePrescriptions throughout the Nordic region and that Nordic ePrescriptions should be able to be retrieved within the EU.

During the session in the autumn of 2021, a political dialogue will be held between the Nordic Council and the Council of Ministers, which gives hope that the issue can be developed further within each country's government.

If the Nordic region is to become the most sustainable and integrated region in the world by 2030, all of the Nordic countries need to start working and connect to the European digital infrastructure and be part of MyHealth@EU (eHDSI) and the European Health Data Space. The time to act is now!

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Glossary of Terms

Acronym	Description
CBeHIS	Cross-Border eHealth Information Services
CDA	Clinical Document Architecture
CEF	Connecting Europe Facility
CEN	The European Committee for Standardization
DSI	Digital Service Infrastructure
eHMSEG	eHealth Member State Expert Group
eHN	eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eP	Electronic Prescription
eP A	Making ePrescriptions available in the country of travel
eP B	Dispensation of foreign ePrescriptions
ePrescription	Electronic prescription
epSOS	Smart Open Services for European Patients
EU	European Union
EUR	Euro
IPS	International Patient Summary
NCPeH	National Contact Point for eHealth
NPÖ	Nationell patientöversikt (national patient overview)
OpenNCP	Open source components – Delivering the software components necessary to run an NCPeH
PS	Patient Summary
PS A	Making a Patient Summary available in the country of travel
PS B	Making a Patient Summary available for citizens of other participating member states

Figure 2 Glossary of terms

1. Introductory remarks

1.1 Assignment

During the Swedish Presidency of the Nordic Council of Ministers in 2018, one of the focus areas was e-health. It was stated that it would be beneficial if the cross-border exchange of e-health data in the Nordic countries could include more countries than Finland and Sweden.

A decision was, therefore, taken to examine the preconditions and develop a plan for continued activities concerning ePrescriptions and Patient Summaries across Nordic national borders as a subproject to *Healthcare and care through distance-spanning technologies (VOPD)*, which is a 2018–2020 priority project (extended to June 2021 due to the Covid-19 pandemic) forming part of the Swedish Presidency Programme of the Nordic Council of Ministers 2018.

The main project is managed by the Centre for Rural Medicine – Region of Västerbotten. The subproject *Cross-border ePrescriptions and Patient Summaries in the Nordic countries* is governed by the Swedish eHealth Agency.

1.2 Delivery

In June 2020, an interim report was published describing the current situation for cross-border ePrescriptions in the Nordic countries and on a European level.

In this final report, the information about cross-border ePrescriptions has been updated. Information on the current situation for Patient Summaries in the Nordic countries and recommendations for continued work on cross-border e-health services has also been added.

In the original project assignment, there was a goal to implement 2-3 pilot projects on ePrescriptions. Unfortunately, that has not been possible, since the necessary legislative changes have not been adopted in Sweden before the main project ends in June 2021.

1.3 Method and implementation of the assignment

The assignment and information gathering for the different countries have been carried out via structured interviews with country representatives identified with the help of the Project Steering Committee. Information regarding the background and current status of the EU cross-border e-health services project has been gathered through previous reports and the Swedish eHealth Agency’s involvement in the European project.

1.3.1 Country representatives

Country representatives in the Nordic cross-border ePrescription and Patient Summary project:

Country	Name of representative	Organisation
Denmark	Kenneth Bøgelund Ahrensberg	The Danish Health Data Authority
Finland	Sari Palojoki Viveca Bergman	Ministry of Social Affairs and Health National Institute for Health and Welfare – THL
Åland[2]	Ulla-Liisa Latvala	Government of Åland
Iceland	Ingi Steinar Ingason	National Centre for eHealth at Directorate of Health
Norway	Irene Olaussen Georg Ranhoff	The Norwegian Directorate of eHealth
Sweden	Carl Jarnling Hans Andersson	Swedish eHealth Agency
(Estonia)	Liisa Lvova	Estonian Health and Welfare Information Systems Centre

Figure 3 Country representatives in the Nordic cross-border ePrescription and Patient Summary project

[2] In Åland, the Finnish implementation of the eP cross-border service is used.

2. Background of cross-border services

2.1 European Union (EU)

2.1.1 Directive on patients' rights in cross-border healthcare

Health issues are handled by the national competence of the EU countries, but the EU can promote cooperation and exchange of information between member states in a range of ways. For several years now, the EU Commission, in collaboration with the member states, has been actively working to support cross-border healthcare, especially regarding e-health. This is intended to promote free movement in the internal market and create opportunities for innovation within the EU.

The cooperation is voluntary and aims to establish an exchange of patient-related information within the Union. The work is mainly based on Directive 2011/24/EU[3] of the European Parliament and the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (Patients' Rights Directive). The Directive addresses the need for information exchange between countries and stipulates that the EU shall promote cooperation and exchange of information between member states on eHealth.

2.1.2 epSOS – the pilot programme that broke new ground for eHealth in Europe

epSOS, meaning "Smart Open Services for European Patients", was a European large-scale pilot programme testing the cross-border sharing of certain health data: the electronic prescription (ePrescription) and a summary of a patient's most important health data (the Patient Summary).

The epSOS project ran for six years (2008-2014) and developed, piloted and evaluated cross-border e-health services and formulated recommendations for future work. The focus was on safe, secure and high-quality services to exchange patient summary data and ePrescriptions between European countries.

The initiative broke new ground and generated much interest in Europe. When the project was initiated in 2008, it involved only a few stakeholders, but it gradually grew to encompass 25 countries and about 50 beneficiaries.

2.1.3 eHealth Network connects authorities responsible for eHealth

The Directive on patients' rights in cross-border healthcare stipulates in Article 14 that the EU shall promote cooperation and exchange of information between member states on eHealth. This takes place within a framework for e-health, the eHealth

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0024

Network (eHN), which connects the national authorities and ministries responsible for e-health.

The work carried out in the eHealth Network is based on the experiences gained in the epSOS project.

The eHealth Network has drawn up rules and specifications for how the exchange takes place in the different areas and has developed requirements to be implemented in the participating countries to achieve sufficient interoperability.

In addition to the Directive, an e-health action plan was developed by the Commission. The plan includes the development of guidelines in several different areas within e-health, including Patient Summaries and ePrescriptions, and a framework for organisational, semantic, technical and legal interoperability.

2.1.4 One National Contact Point for e-health (NCPeH) in each country

According to Article 6 of the Directive, each member state must designate one or more National Contact Points (NCPs) for cross-border healthcare. For e-health issues, the eHealth Network has decided that there should be only one national contact point (NCPeH) in each member state.

To create organisational interoperability, the national e-health contact points shall be interconnected and disseminate information between the countries. The national contact points thus become the only communication channel between the countries for the transmission of data. Only a specific common European network for authorities to exchange information may be used for data transmission (TESTA).

The national contact points are represented in the eHealth Member State Expert Group (eHMSEG), which reports to the eHealth Network. The group's primary purpose is to define and decide on aspects related to the implementation of cross-border e-health services.

2.1.5 MyHealth@EU (eHealth Digital Service Infrastructure, eHDSI)

The epSOS project has been completed, but the work led to what is today called MyHealth@EU and the eHealth Digital Service Infrastructure, eHDSI.

In March 2021, two cross-border MyHealth@EU-services are operational – ePrescriptions and Patient Summaries. Both services aim to convey and translate the respective information into the language relevant in the country of travel.

All EU member states and the European Free Trade Association (EFTA) can participate in exchanging information.

The purpose is to make it easier for patients to seek care, including collecting medicines in another country.

- **ePrescription (and eDispensation)** allows citizens in Europe to retrieve their medication in a pharmacy located in another European country, thanks to the online transfer of their electronic prescription from their country of residence, where they are affiliated, to their country of travel.
- **Patient Summary** provides information on important health-related aspects, such as allergies, current medication, previous illness and surgeries. It will form part of a more extensive collection of health data called the European Health Record, the implementation of which across Europe is planned later. The digital Patient Summary provides doctors with essential information in their own language concerning the patient, when the patient comes from another participating member state and there may be a linguistic barrier. In the longer term, not only the basic medical information of the Patient Summary, but also the complete Health Record should become digitally available across the EU with patient permission.

ePrescriptions and Patient Summaries can be exchanged between participating member states thanks to the eHealth Digital Service Infrastructure (eHDSI) and the NCPeHs, which securely connects the eHealth national services to exchange health data.

2.1.6 IDMP and UNICOM – an improvement

National databases of authorised drugs contain between 5,000 to 20,000 (> 50,000 in Germany) medicinal products, whereas the European Medicines Agency (EMA) database records > 500,000 for all EU member states.

In cross-border ePrescription services, this necessitates substitution of a product in many instances, if not the majority of instances. However, substitution is only possible if the pharmacist can safely identify the medicine specified in the foreign prescription.

The ISO IDMP (IDentification of Medicinal Products) standards specify standardised definitions to identify and describe medicinal products for human use. Their purpose is to facilitate the reliable exchange of medicinal product information robustly and consistently. They help to ensure wide interoperability across global regulatory and healthcare communities, which is critical in ensuring accurate analysis and unambiguous communication across jurisdictions.

Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) requires EU member states, marketing authorisation holders and EMA to use the ISO IDMP standards. This will impact many areas of the pharmaceutical regulatory environment, both in the EU and other regions.

The EMA is in the process of implementing the standards developed by the International Organization for Standardization (ISO) for the identification of medicinal products (IDMP).

UNICOM (Up-scaling the global univocal identification of medicines) is a project with the mission to enable univocal identification of medicinal products by supporting and accelerating the further development, implementation and diffusion of ISO IDMP standards across European health systems. This will facilitate the free flow of semantically coded interoperable drug information across all data users, covering the entire life cycle of a medicine.

The UNICOM project collaborates closely with the eHDSI communities and a pilot project is planned for 2023.

2.1.7 CEN International Patient Summary (IPS)

On behalf of the European Commission, CEN (the European Committee for Standardization[4]) has developed a technology-independent specification of the International Patient Summary information content (EN 17269: 2019 E). It was approved as a standard by CEN on October 7, 2019.

It is based on previous European work but has further detailed and structured the volume of information for increased clarity and to facilitate implementation. At section level, specific rules on the dataset are defined more strictly in the CEN IPS data set than in the current version of the eHDSI guidelines for Patient Summary.

The eHMSEG cannot endorse direct use of the CEN IPS standard EN 17269:2019 as part of the eHDSI artefacts at this moment, but this might be re-evaluated in the future. However, CEN International Patient Summary (IPS) Guidelines should be used as a reference for preparing the subsequent versions of the eHDSI Patient Summary datasets and as guidance for further improvement of the eHDSI CDA implementation guides.

The eHMSEG built the recommendation on the following key points:

- The IPS datasets do not appear to be significantly more difficult to implement for member states preparing to launch eHDSI services than the currently available eHDSI Patient Summary dataset. However, at present all member states cannot implement all optional sections. Some deficiencies have been identified with the availability of data related to mandatory sections for both types of datasets.
- The current CDA implementations of the eHN Patient Summary guidelines already fulfil the IPS dataset requirements to a high degree. Full IPS conformance would require only relatively small changes in the CDA implementation guide.

[4] https://www.cen.eu/Pages/default.aspx

- For member states that are already running routine operations or have already made significant progress in their deployment activities, changes in the CDA implementation guides would require considerable effort to be spent on implementation and testing.

Member state implementations are based on the CDA implementation guides, not on direct use of the eHN guidelines and/or the CEN IPS specification. The licencing and management model that would stem from the immediate use of CEN IPS would bring additional overhead to eHealth DSI management.

2.1.8 Financing

The eHDSI has so far been financed by the member states and the European Union through the Connecting Europe Facility (CEF)[5] programme. However, from 2021 this role will be taken over by the Health and Digital Europe Executive Agency.

The core services are set up and deployed by the European Commission using its resources and through calls for tender financed by CEF. Generic services are funded from national sources and supported by CEF grants through calls for proposals.

Each member state is responsible for the provision of generic services in each country under the eHDSI. This is defined as the preparation, establishment, deployment and operation of the National Contact Point for eHealth (NCPeH) that each country needs for the provision of cross border e-health information services. A national or regional network connecting a wide range of the country's healthcare providers is a prerequisite for connecting them to a European network through the NCPeH.

CEF financing for Generic Services provided a maximum co-financing of EUR 1 000 000 per member state.

Figure 4 DSI – Core and generic services

5 The Connecting Europe Facility (CEF) is a key EU funding instrument to promote growth, jobs and competitiveness through targeted infrastructure investment at a European level.

2.1.9 CEF Calls

The objective of the 2015 CEF Telecom eHealth call was the establishment and operation of National Contact Points for eHealth (NCPeH) to exchange health data and the provision of cross-border ePrescription/e-Dispensation and Patient Summary services. 17 member states were granted funding and the first member states began exchanging health data in January 2019.

In the 2017 CEF Telecom eHealth call, 8 member states were granted funding, of which 2 were for adding an additional service.

In the 2019 CEF call, 8 member states were granted funding, of which 5 were for adding an additional service.

Denmark, Iceland (EFTA), Norway (EFTA) and Romania have not applied or received CEF funding.

The following member states received CEF funding in the 2015, 2017 and 2019 CEF calls.

Acronyms
PS A – Making Patient Summary available in the country of travel
PS B – Making Patient Summary available for citizens of other participating member states
eP A – Making ePrescriptions available in the country of travel
eP B – Dispensation of foreign ePrescriptions

Country	ePrescription	Patient Summary	Comment
Austria	A & B	A & B	Withdrawn
Belgium		A & B	On hold
Bulgaria	A & B	A & B	
Croatia	A & B	A & B	
Cyprus	A & B	A & B	
Czech Republic	A & B	A & B	
Estonia	A & B	A & B	
Finland	A & B	A & B	
France		A & B	
Germany		A & B	
Greece	A & B	A & B	
Hungary	A & B	A & B	
Ireland	A & B	A & B	
Italy	A & B	A & B	
Latvia	A & B	A & B	
Lithuania	A & B	A & B	
Luxemburg	A	A & B	
Malta		A & B	
Netherlands		B	
Poland	A & B		
Portugal	A & B	A & B	
Slovakia		A	
Slovenia	A & B	A & B	
Spain	A & B	A & B	
Sweden	A & B		

Figure 5 Member states who received CEF funding in the 2015, 2017 and 2019 CEF calls

By 2023, both services will gradually be implemented in 24 participating countries.

In January 2019, Estonia and Finland were the first countries to implement the cross-border ePrescription service. In March 2021, ePrescriptions can be exchanged between Finland, Estonia, Croatia and Portugal. Patient Summaries can be exchanged between Croatia, Czech Republic, Luxembourg, Malta and Portugal.

2.2 Nordic countries

2.2.1 Four Nordic countries participated in the epSOS project

Denmark, Finland, Norway and Sweden participated in the epSOS project with the ePrescription service. Both Finland and Sweden intended to participate in both the ePrescription and the Patient Summary services, but they concentrated on the ePrescription service due to the legal situation. E-prescriptions were exchanged and it was agreed that cross-border exchange of health data would be beneficial for citizens in the Nordic countries.

When the epSOS project was concluded in 2014, there was no clear plan to continue the cross-border exchange of e-health data in Europe.

During the Swedish Presidency of the Nordic Council of Ministers in 2014, it was consequently decided that the Nordic countries would look into the opportunities to continue exchanging ePrescriptions across the Nordic borders, regardless of what happened on the European level.

However, when the work began in 2015, activities on the European level were formalised, and it was decided that the Nordic project would continue as part of the European initiative.

2.2.2 Swedish Presidency 2018 – focus on e-health

During the Swedish Presidency of the Nordic Council of Ministers in 2018, one of the focus areas was e-health. It was identified that it would be beneficial if the cross-border exchange of e-health data in the Nordic countries could include more countries than Finland and Sweden.

Therefore, the decision was taken to examine the preconditions and develop a plan for the continued development of activities concerning ePrescriptions and Patient Summaries across Nordic national borders as a subproject of *Healthcare and care through distance-spanning technologies*.

2.2.3 A decision in the Nordic Council

In October 2019, at the 71st session of the Nordic Council, a unanimous decision (62-0) was taken that the Nordic Council would recommend that the Nordic Council of Ministers prioritise cross-border ePrescriptions in all Nordic countries. The vision was that all Nordic citizens would be able to retrieve ePrescriptions at pharmacies throughout the Nordic region and that Nordic ePrescriptions would be retrieved within the EU.

The Nordic Council of Ministers has responded that they view the Nordic Council's recommendation as strong support for the work that is already in progress. Still, that full implementation is only possible when technical and legal conditions have been met.

During the session in the autumn of 2021, a political dialogue will be held between the Nordic Council and the Council of Ministers, which gives hope that the issue can be taken further within each country's government.

3. ePrescriptions in the Nordic countries – current status

3.1 Cross-border ePrescriptions is progressing fast

The separate Nordic countries are already at the forefront when it comes to the use of ePrescriptions nationally, with ePrescriptions representing 98-100 per cent of prescriptions.

In Europe, there are still countries that do not use ePrescriptions, for example, France. However, this is changing rapidly and in some countries the cross-border ePrescription service is seen as a driver in introducing or further developing the national ePrescription service.

18 countries already plan to implement cross-border ePrescriptions by 2023. With new calls for funding, more countries are expected to implement cross-border ePrescriptions.

3.2 Finland and Sweden are the only Nordic countries participating in the EU project

From the Nordic countries, Finland and Sweden are currently participating in the European project on cross-border ePrescription services, in addition to Estonia, Latvia and Lithuania from the Baltic states.

In March 2021, 18 of the EU's 27 member states plan to introduce the cross-border ePrescription service. The following table describes the intended go-live years[6].

Acronyms

PS A – Making Patient Summary available in the country of travel
PS B – Making Patient Summary available for citizens of other participating member states
eP A – Making ePrescriptions available in the country of travel
eP B – Dispensation of foreign ePrescriptions

Member state	2019-20	2021	2022	2023
Croatia	A & B			
Estonia	A & B			
Finland	A & B			
Portugal	A & B			
Cyprus		A & B		
Czech Republic		A & B		
Greece		A & B		
Ireland		A		B
Luxembourg		A		
Poland		A & B		
Hungary			A & B	
Latvia			A & B	
Lithuania			A & B	
Slovenia			A & B	
Spain			A & B	
Sweden			A & B	
Bulgaria				A & B
Italy				A & B

Figure 6 ePrescription – member state-planned go-live year

Austria, Belgium, Denmark, France, Germany, Iceland (EFTA), Malta, Norway (EFTA), the Netherlands, Romania, and Slovakia have not announced that they will implement ePrescription services.

[6] Källa: https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=222532498

3.3 Denmark

3.3.1 National ePrescriptions

In Denmark, the Danish Health Data Authority is responsible for storing and transmitting ePrescriptions.

In Denmark, prescriptions are issued with the medicinal product's product name and, at present, 100 per cent of Danish prescriptions are ePrescriptions.

The Shared Medication Record (Fælles Medicinkort) is a central database holding data on all Danish citizens' electronic prescriptions and medication purchases over the preceding two years, as well as an updated list of citizens' current prescribed medications. It also holds data on vaccinations.

The Shared Medication Record aims at preventing incorrect medication and provides an overview of citizens' current medication. Furthermore, the Shared Medication Record gives all patients and the healthcare professionals treating a patient access to updated information about their medication for those healthcare professionals integrated into the system that are supporting the patient's treatment.

The Shared Medication Record is an electronic tool that health professionals can use to view information about a citizen. Health professionals can also register, update and change information regarding medications directly in their own system, integrating the Shared Medication Record directly into the local system. Furthermore, citizens can see information about their current prescriptions, as well as the last two years of prescriptions, and can access the record via an app, which also provides the option of renewing prescriptions.

Parents have access to information about their children's medications and vaccinations. However, since custody only became an integral part of the registry in May 2007, parents cannot see information for those born before 28 May 2004.

3.3.2 Cross-border ePrescriptions

Background

Denmark was active in epSOS and participated with the ePrescription service, and a very limited number of ePrescriptions were exchanged with Sweden.

eHDSI participation

There is no appointed National Contact Point for eHealth in Denmark, but a logical alternative would be the Danish Health Data Authority.

Denmark applied for CEF funding in the 2015 call but was not granted funding for their ePrescription services.

In 2019 Denmark assessed whether to apply for CEF funding in the 2019 CEF call.

It is considered that, at present, some central preconditions for Danish participation in activities for the exchange of cross-border health information have not been met.

This is primarily due to:

- the experience gained from the epSOS project. Since the resources involved in participating in epSOS far exceeded the gains, the Danish approach has since been that a real and positive business case must be presented as a prerequisite to participation in projects of this nature.
- uncertainty regarding the establishment and operating costs of the Danish connection to eHDSI and their financing. Each member state must finance the operating costs.
- lack of Danish demand for the solution.

Future plans

Denmark is not actively working on ePrescription cross-border services but will follow developments and reassess participation in the future.

3.4 Finland

3.4.1 National ePrescriptions

In Finland, ePrescriptions are issued, i.e. there are no paper prescriptions. Paper and telephone prescriptions can be used in exceptional situations when there are technical problems. In these cases, the pharmacy converts the prescriptions into electronic form and records them in their Prescription Centre.

ePrescriptions are stored in the Prescription Centre, which is part of the Kanta Services. The Prescription Centre contains all of the ePrescriptions and the pharmacy's notes on their dispensing.

In Finland, a prescription can be issued using either the product name of a pharmaceutical or the active substance's name in the medication.

In Finland, a prescription is valid for two years from the date of issue or renewal. However, prescriptions for medications that affect the central nervous system and medications classified as narcotics are only valid for one year.

All Finnish pharmacies are connected to the Prescription Centre.

All pharmacies in Finland use the Kanta Services to obtain the information they need to dispense a prescription.

3.4.2 Cross-border ePrescriptions

Background

Finland was very active in epSOS and participated with the ePrescription service, and ePrescriptions were exchanged with Sweden during the project.

eHDSI participation

Finland applied for CEF funding in the 2015 call and was granted EUR 655,230 for their ePrescription services.

In Finland, the national contact point for eHealth is placed with Kansaneläkelaitos Kela (in Swedish "Folkpensionsanstalten FPA")[7]. The contact point is part of the Kela activities.

Finland is an active member of the collaboration and chaired eHMSEG 2018-2020. Finland actively participates in the working groups under eHMSEG, e.g., the Semantic Task Force, Legal Work Group, ePrescription Cluster, Patient Summary Cluster and the Technical Work Group (Open NCP).

In January 2019, Finland and Estonia were the first countries to implement cross-border ePrescription services. Finnish ePrescriptions can, as of March 2021, be dispensed in Estonia, Croatia and Portugal.

In 2020, Finland launched the service to dispense ePrescriptions from other participating member states in Finland. ePrescriptions from Estonia, Croatia and Portugal can now be dispensed.

Legal

To secure the legality of the exchange of data necessary within eHDSI, Finland amended its Act on Electronic Prescription in 2013/2014.

Paragraph 23 a § in the law:

https://www.finlex.fi/sv/laki/ajantasa/2007/20070061#L5P23a

Future plans

Now that the ePrescription cross-border services have been implemented, the main task is to develop the existing solution further and connect more member states, both for making Finnish ePrescriptions available for dispensing abroad and dispensing ePrescriptions from participating member states in Finland.

[7] Kansaneläkelaitos Kela (in Swedish "Folkpensionsanstalten FPA"), the Social Insurance Institution of Finland, is a government agency that provides basic financial security for everyone living in Finland.

3.5 Iceland

3.5.1 National ePrescriptions

In Iceland, prescriptions are issued with the product name of the pharmaceutical and at present 98-99 per cent of all prescriptions in Iceland are ePrescriptions.

3.5.2 Cross-border ePrescriptions

Iceland is not a member of the eHealth Network.

There is no appointed National Contact Point for eHealth in Iceland, but a logical alternative would be the Directorate of Health

Iceland did not participate in epSOS, did not apply for CEF funding, and is not actively working on the ePrescription cross-border services.

3.6 Norway

3.6.1 National ePrescriptions

In Norway, prescriptions are issued with the product name of the pharmaceutical and at present more than 90 per cent of all prescriptions in Norway are ePrescriptions.

In Norway, the Norwegian Directorate of eHealth (Direktoratet for e-helse) is responsible for developing, introducing, and administering national e-health services, such as any ePrescription, summary care record and electronic patient records.

The Prescription Intermediary (Reseptformidleren) is a national database for electronic prescriptions and includes information on prescription drugs that patients have received. The Prescription Intermediary aims to provide secure and efficient electronic dissemination of prescriptions and prescription information.

The Prescription Intermediary handles all of the prescription information and ensures that the correct prescription information is shared between a patient’s healthcare professionals.

After a prescription has been dispensed from a pharmacy, the Prescription Intermediary displays the prescription for 30 days before the information is deleted and is no longer visible in the Prescription Intermediary. If the prescription is not dispensed at a pharmacy, it is deleted when the prescription period has expired.

Prescription information in the Prescription Intermediary is passed on to the Summary Care Record (Kjernejournalen[8]), where the drug history summary will cover up to the past three years.

The Summary care record contains a list of current prescriptions and a summary of the medicines that have been dispensed via prescription by Norwegian pharmacies. Medicines purchased without a prescription, received from an out-of-hours medical center, hospital or nursing home, or purchased abroad will not be shown.

3.6.2 Cross-border ePrescriptions

Background

Norway participated in epSOS as observer.

eHDSI participation

There is no appointed National Contact Point for eHealth in Norway and the organisation to be responsible for NCPeH in Norway has not yet been decided.

Norway assessed whether to apply for CEF funding in the CEF call 2017 and decided not to apply.

Norway also assessed whether to apply for CEF funding in the 2019 CEF call. The Norwegian Directorate of eHealth recommended the Ministry of Health and Care Services not to apply for funding.

The main reasons for the recommendation were that a thorough study would be required to understand the consequences (technical, semantic, organisational, legal) of participation and that the cost of participation would be so high that it would be at the expense of already-prioritised national measures.

EU funding is not a prerequisite to participate and work for adaption to the infrastructure.

Norway participates in some groups – e.g. eHMSEG and X-eHealth – and actively follows the cross-border development.

[8] The Kjernejournal (Summary Care Record) contains selected and important information about individuals' health. The Kjernejournal gives health care professionals immediate access to selected and important information about a patient's health, regardless of where the treatment was received.

This means that healthcare professionals spend less time looking for information about each patient before treatment can start. When a case is urgent, this could have serious consequences.

The Kjernejournal complements the medical records kept by general practitioners, out-of-hours services and hospitals.

Future plans

If a strong momentum for the exchange of ePrescriptions in the Nordic countries were to arise, it could trigger a new process and reassessment of more active participation.

3.7 Sweden

3.7.1 National ePrescriptions

In Sweden, the Swedish eHealth Agency is responsible for storing and transmitting ePrescriptions.

In Sweden, prescriptions are issued with the product name of the pharmaceutical and at present 99 per cent of all prescriptions are ePrescriptions.

When a prescriber sends an ePrescription, it comes to the National Medication List, a national repository for which the Swedish eHealth Agency is responsible.

The ePrescriptions are stored in the National medication list while waiting for the patient to retrieve his/her medication at a pharmacy. The information is saved for a maximum of 15 months after the last registration.

All pharmacies in Sweden use the eHealth Agency databases to obtain the information they need to dispense a prescription.

3.7.2 Cross-border ePrescriptions

Background

Sweden was very active in epSOS and led the project in 2008-2014.

The original plan was that Sweden would participate in both ePrescriptions and Patient Summary. However, due to legal restraints, only the service for ePrescription was implemented.

ePrescriptions were exchanged with Denmark, Finland and Croatia during the project.

eHDSI participation

Sweden applied for CEF funding in the 2015 call and was granted EUR 791,092 for its ePrescription services.

The Swedish eHealth Agency is Sweden’s National Contact Point for eHealth in the European eHealth initiative.

The Swedish eHealth Agency actively participates in the working groups under eHMSEG and leads the eP Cluster, which works with current issues concerning ePrescriptions. The Agency also leads the Semantic Task Force, which further develops the semantic regulations and associated services.

The Swedish eHealth Agency also participates in the Legal Work Group and contributes developer and architectural expertise to the Technical Work Group, which further develops software intended to be used by the national contact points (Open NCP).

Legal

To secure the legality of the exchange of data necessary within eHDSI, the necessary amendments to applicable legislation must be made.

To ensure that legal conditions exist for cross-border e-health services, the Swedish eHealth Agency has delivered a report[9] with an investigation of the changes required and proposals for the legal changes necessary for the Agency's handling of cross-border ePrescriptions. Amendments have been proposed to *lagen om nationell läkemedelslista* (the National Medication List Act), *offentlighets- och sekretesslagen* (the Public Access to Information and Secrecy Act) and *förordningen med instruktion för E-hälsomyndigheten* (the eHealth Agency Instruction), which will allow disclosure of the data in the National Medication List to dispensing pharmacists in other European countries that participate in the exchange to dispense ePrescriptions. The Agency has also proposed a new regulation for data processing that will take place when dispensing ePrescriptions from participating member states in Sweden.

The report forms an essential basis for the investigation that the Ministry of Health and Social Affairs has implemented to submit proposals for national regulation. With a focus on security and integrity, it will review the uncertainties that remain in the legislation. The work will be reported to the Ministry in September 2021.

Also, the eHealth Agency has entered into agreements with all pharmacies in Sweden.

Future plans

The ePrescription services will technically be ready to go live in 2021. The organisational and technical conditions for the ePrescription services are made as far as possible before the legal conditions are in place. When there is a timetable for the legal conditions, the Swedish eHealth Agency can complete what is necessary to implement cross-border ePrescription services.

[9] E-hälsomyndigheten. Reglering av personuppgiftsbehandling. Diarienummer 2018/02557.

The cross-border ePrescription service is a priority initiative in the Swedish vision for e-health 2025 and the action plan 2020-2022. The service is, thereby, the subject of attention.

When the ePrescription cross-border services have been implemented, the main focus will be on developing the existing solution further and connecting more member states, both for making Swedish ePrescriptions available for dispensing abroad and dispensing ePrescriptions from participating member states in Sweden.

4. Patient Summaries in the Nordic countries – current status

4.1 Cross-border Patient Summary

The conditions for compiling a Patient Summary are very different in the different European countries. Information management can, for example, be national/regional, managed centrally/decentralised, derive from state/private health care facilities or be mandatory/voluntary to share.

At present, no country can provide all of the information in the cross-border Patient Summary. However, the aim is for all countries to provide all of the information and each country must, therefore, develop an action plan on how to achieve this. For the time being, the information available will be presented on the assumption that this information may also be life-changing.

Work is ongoing to find solutions to enable member states to present as much information as possible.

At present, the Patient Summary is designed for unplanned care. However, there is ongoing work to make the Patient Summary also available for planned care.

4.2 Finland is currently the only country working with cross-border Patient Summary

At present, 22 of the EU's 27 member states plan to introduce the cross-border Patient Summary service.

The following table describes the aimed go-live years[10].

Acronyms

PS A – Making Patient Summary available in the country of travel
PS B – Making Patient Summary available for citizens of other participating member states
eP A – Making ePrescriptions available in the country of travel
eP B – Dispensation of foreign ePrescriptions

Member state	2019-20	2021	2022	2023	2024
Croatia	A & B				
Czech Republic	A & B				
Luxembourg	A & B				
Malta	A & B				
Portugal	A & B				
Cyrus		A & B			
Estonia		A & B			
France		B	A		
Greece		A & B			
Ireland		A		B	
Spain		A & B			
Germany			A & B		
Hungary			A & B		
Italy			A & B		
Netherlands			B		
Slovakia			A		
Slovenia			A & B		
Belgium				A & B	
Bulgaria				A & B	
Finland				A	B
Latvia				A & B	
Lithuania				A & B	

Figure 7 Patient Summary – member state-planned go-live year

Austria, Denmark, Iceland (EFTA), Norway (EFTA), Poland, Romania and Sweden have not announced that they will implement the Patient Summary services.

[10] Källa: https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=222532498

4.3 Denmark

4.3.1 National Patient Summary

The Danish National Patient Summary is decentralised and shares data across sectors on patients about their medicines, laboratory results, electronic health records, imaging etc. The Patient Summary, which covers all citizens, is accessed via an app called MinSundhed (My Health), the national health portal sundhed.dk and the app Min Læge (My Doctor). These solutions provide access to data stored in local systems as well as national databases.

4.3.2 Cross-border Patient Summary

Background and eHDSI participation

Due to limited demand, Denmark did not participate in epSOS with Patient Summaries and did not apply for funding in the CEF calls.

Future plans

In light of recent developments regarding both the European Health Data Space (see chapter 6.1) project and the Nordic work, Denmark is considering the Danish cross-border services position. However, in order to allocate resources and decide how to proceed, the Covid-19 pandemic must first be resolved, as issues related to the pandemic are higher on the agenda.

4.4 Finland

4.4.1 National Patient Summary

There is no concept of “Patient Summary” in Finland in the same way as in the eHDSI Patient Summary. However, there are parts of the Patient Summary, such as a diagnosis/problem summary, risk/allergy summary and laboratory summary.

The contents are not precisely the same as in eHDSI. Not all sections can be provided and not all fields in the sections are currently available. Extensions of some parts are planned for the future. Summaries are generated in the CDA format but not in accordance with the eHDSI CDA implementation guides. Instead, nationally defined implementation guides are used.

Data is entered in health care organisations as part of the standard treatment process documentation and stored in the Kanta services (Patient Data Repository). Entries are collected from care documents in the summary service, which can then return summaries on request.

The system is relatively new. It entered into production in 2020 and does not contain all of the older data entries, but some entries have been populated from older care documents.

The Kela (social insurance institution) is responsible for the maintenance of the Kanta services. The data is not in a single registry but is logically separated in Kanta into registers of data controllers that have stored the data.

All public healthcare providers are connected to Kanta and the vast majority of private healthcare providers. Not all systems are yet able to produce data in a fully structured form (according to specs issued in 2016), but the situation is improving gradually.

4.4.2 Cross-border Patient Summary

Finland applied and received CEF funding for the Patient Summary service in the 2019 CEF call. The plan is to make Finnish Patient Summaries available in other participating countries by the end of 2023 and open the service for foreign Patient Summaries in Finland by 2024 with national coverage. The cross-border Patient Summary will be part of the Kanta services.

In March 2021, a comparison between national and cross-border data is ongoing to decide which information can be included in the cross-border Patient Summary. Expanding the data content of the Kanta services is not part of the cross-border initiative. However, as the Kanta services are developed nationally to be more structured, data will be added to cross-border Patient Summary.

The technical solution will build on OpenNCP with a national Patient Summary connector. A portal solution will likely be offered in addition to interfaces to be consumed by local systems.

Current legislation only permits prescription data to be transferred cross-border. The legislation, therefore, needs to be amended also to include patient summary information.

4.5 Iceland

4.5.1 National Patient Summary

In Iceland, patient records are shared nationally and are accessible to all healthcare personnel caring for the patient, anytime, anywhere.

All primary healthcare clinics and hospitals share patient information on a national level via the Icelandic HealthNet Hekla. Most private specialty services and nursing homes are also a part of the interconnected electronic health record.

Laws and regulations allow the sharing of patient records between different healthcare institutions and across varying levels of health services. All health records are shared, not just the patient summary.

4.5.2 Cross-border Patient Summary

Background and eHDSI participation

Iceland did not participate in epSOS with Patient Summaries and did not apply for funding in the CEF calls.

Future plans

Iceland is not currently working on Patient Summary cross-border services. However, Iceland participates in the Nordic eHealth group and its subgroup, the Nordic Standardization group. The eHealth group is under the auspices of the Nordic Council of Ministers. The Standardization group has recommended that the International Patient Summary standard be used in the Nordic countries to share patient information across borders. Hence, Iceland will adhere to the IPS standard for cross-border patient information sharing.

4.6 Norway

4.6.1 National Patient Summary

The Summary care record (Kjernejournalen) is an online service that contains essential information about the citizen´s health. Both the citizen and healthcare professionals have access to the information in the service.

The Summary care record service was introduced in 2013. It is available in all hospitals in Norway. It has been implemented across every municipality and county, but a few out-of-hours medical centres and medical clinics have not yet introduced the service.

All permanent residents in Norway have been given a Summary care record, except for a minimal number of people who have opted out of the system.

The Norwegian Health Net (NHN) is responsible for the service. Citizens have access via the national service Helsenorge.no.

Summary care records collate information from multiple sources.

Critical information in the Summary care record is health information that could be vital for healthcare professionals to know in an emergency. The information could influence the type of examination, treatment or follow-up that a hospital chooses.

Critical information will not be added to a Summary care record until the doctor has registered it.

Examples of critical information:

- severe allergies or hypersensitivity reactions, such as allergy to penicillin and previous narcosis issues
- implants, such as prostheses and pacemakers
- necessary treatment that the patient is receiving, such as dialysis
- changes to treatment routines and decisions that deviate from the normal routine, such as blood transfusion and life-prolonging treatment
- rare, severe conditions, such as haemophilia

Information that is not recorded in the Summary care record:

- all previous diagnoses
- notes from Patient records
- blood test results and other examination results

The immunisation status can be viewed via a link in the Summary care record to the Norwegian immunisation registry SYSVAK.

A digital donor card can also be added to the Summary care record.

The Summary care record contains a list of a patent's current prescriptions and a summary of the medicines that have been dispensed via prescription by Norwegian pharmacies.

Information about a patient's contacts with hospitals and the specialist health service is added to the Summary care record, so that healthcare professionals can obtain a complete picture of a patient´s health.

Citizens can help to improve their Summary care record by entering information into the record. It will help healthcare professionals getting a complete picture of the citizen´s health. This information could include:

- Next of kin – people whom healthcare professionals can contact.
- Special communication needs – information on challenges relating to vision, hearing, speech or language.
- Medical history – previous health conditions or diseases that healthcare professionals should be aware of.

4.6.2 Recommendation to follow the CEN-IPS standard

The Norwegian Directorate for e-Health has significant interest in and commitment to the European standard CEN-IPS (EN 17269) nationally and internationally. Norwegian actors have requested recommendations on how to implement the standard.

Therefore, in autumn 2020, a national recommendation to follow the IPS standard for national purposes (Versjon HITR 1240:2020) was published. The recommendation is a normative document[11].

Many implementation activities are expected in Norway to structure medical records, interaction with and the secondary use of data. An overall framework gives the activities a common direction and can stimulate companies and suppliers to develop the necessary implementation guides. It will further strengthen the quality of documentation, patient safety and reuse of data.

A European standard, prepared by a recognised European standardisation organisation such as CEN, also provides predictable development, involvement and management for Norwegian actors.

Use of the standard entails an adaptation to European guidelines and standardisation work, in line with the recommended direction in the Digitization Circular[12] and the Digital Agenda for Norway[13]. This will reduce the gap with the European market.

Adapting to European guidelines will facilitate the transition to any future requirements for exchanging health information in Europe. It will also enable cross-border health services goals as defined in the EU Patient Rights Directive (Article 14), which also applies to Norway.

To safeguard Norwegian interests, the actors in the sector in Norway should contribute to the work of influencing the further development of work on summary patient information in Europe and internationally, including:

- Further development of NS-EN 17269
- Preparation of implementation guides and profiles
- Use of terminology and coding.

4.6.3 Cross-border Patient Summary

Background and eHDSI participation

Norway participated as observer in epSOS from 2011 until the project ended in 2014.

[11] Veiledere - Provides advice in specific areas based on best practice from several operations.
[12] https://www.regjeringen.no/no/dokumentarkiv/regjeringen-solberg/andre-dokumenter/kmd/2019/digitaliseringsrundskrivet/id2683652/
[13] https://www.regjeringen.no/no/dokumenter/meld.-st.-27-20152016/id2483795/?ch=1

So far, Norway has decided not to commit to cross-border exchanges with Patient Summaries. New assessments will be done, but it has not yet been decided when this will happen.

The Covid pandemic has reaffirmed the importance of European cooperation. Norway is participating in work on the Digital Green Certificate.

Future plans

Norway is following closely and participating in the European work and is taking action to align the national services on a semantic level with the European guidelines.

4.7 Sweden

4.7.1 National Patient Summary

Patient Summaries have existed in Swedish health and medical care for many years, mainly in regions and municipalities through the national patient overview service, Nationell patientöversikt – NPÖ. It makes it possible to access and make available medical record information across care providers' organisational boundaries and various systems via the national service platform.

The amount of information presented in a Patient Summary varies, because it is voluntary for each care provider to provide information via the service platform and participate in the NPÖ. The care provider also decides to what extent the provider's information is to be shared.

Private care providers without public funding are not included.

4.7.2 Cross-border Patient Summary

Current status

In the spring of 2019, the Swedish eHealth Agency was commissioned to analyse the information management that needs to be carried out in Sweden for Patient Summaries.[14]

The final report[15], presented on 30 June 2020, contains an analysis of operational, semantic, technical and legal issues regarding Sweden's information management. Based on previous experience in working with cross-border ePrescriptions, one lesson is that the legal aspects need to be elucidated at an early stage.

[14] Regeringsuppdrag från Socialdepartementet. Uppdrag angående informationshantering vid utlandsvård. Diarienummer S2019/01519/FS 2019.
[15] E-hälsomyndigheten. Informationshantering vid utlandsvård. Diarienummer 2019/01537.

The Swedish conditions for a Patient Summary that can be shared with other European countries within the European initiative have been analysed in the report. One goal was to identify measures that can both support European exchange and, at the same time, improve and further develop the national Patient Summary. Alternative solutions were evaluated and the most promising solutions are presented with a more detailed analysis in the report.

The report also contains an overview of the measures that need to be implemented in each area (operational, semantic, technical and legal) to enable a European exchange of information.

The report shows that Sweden has good conditions for exchanging Patient Summaries across national borders in terms of information and technology. The main reason for this is that Sweden already has a national Patient Summary (Nationell patientöversikt, NPÖ) with an established administration that uses common technical services for information provision.

The information content and code systems used in the NPÖ correspond well with the Cross-border Patient Summary, with some need for supplementation in the form of five specifications for new supplementary national information domains. The national contact point for e-health has also already been designated for the work with cross-border ePrescriptions. Still, it needs to be developed further to enable the exchange of Patient Summaries. Also, some legal measures are required for the legal conditions to exchange Patient Summaries across national borders.

Based on the national conditions, a solution has been suggested, where existing infrastructure is reused as far as possible. This is, among other things, to take advantage of what already exists, to avoid introducing more solutions for healthcare with new requirements for their providers and to be able to connect to European services as soon as possible. Emphasis has also been placed on solutions following established standards and frameworks, both international and Swedish ones.

With regards to the legal measures, amendments will be needed to *patientdatalagen* (the Patient Data Act), *lagen om nationell läkemedelslista* (the National Medication List Act), *offentlighets- och sekretesslagen* (the Public Access to Information and Secrecy Act). A new regulation on personal data processing at the eHealth Agency in connection with cross-border health and medical care is also necessary.

For the scenario where a Swedish patient seeks care abroad, a solution is recommended, which means that the information is retrieved, if necessary, from the Swedish care providers' record system and the National Medication List's register.

For the scenario where a foreign patient seeks care in Sweden, a solution is recommended, whereby the NPÖ client is supplemented with the opportunity to receive and present foreign care information. This allows Swedish healthcare staff to access data from foreign healthcare systems via established tools to access medical record information.

Future plans

Sweden has not applied for funding of the Patient Summary services in the CEF calls. The Swedish government has not communicated any more planned work or activities in the area of cross-border Patient Summaries.

5. Lessons learned – areas that should be considered at an early stage

In this chapter, lessons learned that have been identified when working within the European project are presented. It focuses on issues that have taken a long period of time or that have been difficult to manage for different countries.

The lessons learned can inspire what should be considered at an early stage in national projects working with cross-border healthcare information.

5.1 General

5.1.1 National legislation

Most member states have amended or will need to make amendments to applicable legislation to secure the legality of the exchange of data necessary within eHDSI.

Lessons learned from most of these member states are that it is very time-consuming, in calendar time, to amend a law. It takes time to study what needs to be changed, assess the changes, and then decide to update the legislation and introduce it.

For examples of amendments in Finland and Sweden, see Chapters 3.4.2 and 3.7.2.

5.1.2 Data security and TESTA

The exchange of information between member states is carried out in a separate, secure network called TESTA.

Getting access to TESTA does not present a problem for most member states, for example, for Finland.

However, for other member states, for example, Sweden and Germany, this process has been very time-consuming.

The recommendation is, therefore, to begin implementing access to TESTA as soon as possible.

5.2 ePrescriptions

5.2.1 Paper prescriptions vs ePrescriptions

When changing from paper prescriptions to ePrescriptions, everything becomes much more “right or wrong”. With paper prescriptions, it is up to the pharmacist to decide, but with ePrescriptions, much is determined by the system.

There are many benefits from ePrescriptions, but it is difficult to maintain the benefits provided by paper prescriptions.

In discussions with other member states, it is very easy to demand exact answers. Yet, when asked the same question, it is tempting to ask for freedom to decide outside the framework, saying that the pharmacist should decide, not the system. However, in this early stage of the services, the answer must be that it should be “right/wrong”.

Later, with experience from the services implemented, regulations may be eased where reasonable.

5.2.2 Prescribing – Generic/Product

Within Europe, there are differences in how medication is prescribed. In Sweden, for example, medication is prescribed by product. In Estonia, it is prescribed by substance, which is called a generic prescription. In Finland, a prescription may be generic or product.

In general, this does not present a problem. However, when it comes to substitution, this may generate different views between member states.

Most member states only allow generic substitution. One reason for substitution is to reduce medication costs (change to the cheapest product). Substitution is optional when the prescription includes the product name. In most countries, the prescriber can indicate that substitution is not possible.

5.2.3 National product catalogues

The fact that pharmaceuticals have different product names in different member states means that it is impossible to have a joint product catalogue.

Different countries also have different rules. Overall, this means that the management of exchange and substitution is complicated.

Units are expressed in different ways in different member states. The result is precisely the same, but it is difficult for the systems to understand it. This is an example of the problems that may arise when prescribing a product or a generic.

5.3 Patient Summary

5.3.1 National content vs European content

Providing structured and coded data for all sections is complicated and time-consuming to implement. Therefore, it is beneficial, as soon as possible, to structure the data in the national systems in line with the European standards.

The countries that are now working to introduce cross-border Patient Summaries in Europe testify that the cross-border Patient Summary is an essential driver in further developing and driving the development and use of national Patient Summaries.

6. Plan for continued work in Europe

The recent worldwide Covid-19 pandemic health crisis has reminded us that health crises respect no borders and affect all. More than ever before, the access to and sharing of health data are gaining a new sense of urgency and relevance. This is why health care systems are part of the EU core values.

6.1 European Health Data Space (EHDS)

The Commission President Ursula von der Leyen has announced the European Health Data Space, of which My Health @ EU (eHDSI) is a cornerstone, as a top priority with a legal proposal in 2021.

The European Health Data Space will:

- promote the safe exchange of patients' data (including when they travel abroad) and citizens' control over their health data
- support research on treatments, medicines, medical devices and outcomes
- encourage the access to and use of health data for research, policy-making and regulation, with a trusted governance framework and upholding data-protection rules
- support digital health services
- clarify the safety and liability of artificial intelligence in health.

6.2 New services

6.2.1 X-eHealth – new cross-border services

The EU-funded X-eHealth project started in September 2020 and will end in 2022. It aims to lay the groundwork for a practical, interoperable, secure and cross-border Electronic Health Record exchange Format (EHRxF), contributing directly to eHDSI evolution and additional usage within member states on national, regional or local levels.

In practice, X-eHealth will build upon the existing Patient Summary service and lay the foundations for a common structure for the following use cases:

- **Medical imaging**
  Imaging has revolutionised healthcare. Many new techniques have been introduced in recent decades that support healthcare and refine healthcare diagnostic and therapeutic possibilities. Imaging techniques are used in all healthcare processes, from prevention, diagnosis and intervention through to follow-up.
- **Discharge letters**
  A hospital discharge is the formal release of a patient from a hospital after a procedure or course of treatment. A discharge occurs whenever a patient leaves because of finalisation of treatment, signs out against medical advice, transfers to another health care institution or upon death.
- **Laboratory results**
  Clinical laboratory results play an important role in the diagnosis, treatment and follow-up of patients.
- **Rare diseases**
  The lack of visibility of the diagnosis of a rare disease patients' records can result in harmful consequences for the patients. In some specific situations, i.e. when patients find themselves in healthcare situations outside their used expertise environment, identifying these patients as suffering from a given rare disease to allow to access helpful information (in particular best practice guidelines), as well as the expert centre following the patient, is crucial delivering the best care to these patients and avoiding preventable complications.

The exchange of these new services is planned for 2023.

6.2.2 Original Clinical Document, OrCD

Considering that there is already a need for information on laboratory results, medical imaging and discharge letters, the eHDSI requirements for a new use case, Original Clinical Documents, were adopted by the eHMSEG in June 2020. The exchange of Original Clinical Documents will start in 2022.

The Original Clinical Documents exchange shall be understood to include the original clinical document provided by the country of affiliation to the country of treatment for access by health professionals, without being subject to any clinical content processing.

The new use case does not affect the current eHDSI use cases and specifications to exchange Patient Summaries and ePrescriptions/eDispensations documents.

Implementation of the new use case is voluntary. However, to do so, at least one of the original use cases must be implemented. The go-live process for the new service should follow the relevant eHDSI procedures. The new service should need to be tested and audited in a similar manner to the current ePrescription and Patient Summary services.

6.3 Funding

Funding is not a prerequisite for participation in the eHDSI cross-border services. A member state can decide to join without funding from the EU.

The eHDSI has so far been financed by the member states and the European Union through the Connecting Europe Facility (CEF)[16] programme. From 2021 this role will be taken over by the Health and Digital Europe Executive Agency, which in the fall of 2021 will launch a call for grants with the aim to increase the geographic coverage and scope of MyHealth@EU (eHDSI):

- by setting up National Contact Points for eHealth to aggregate patient information from national electronic health records or other infrastructure and share it cross-border;
- broadening the coverage of ePrescriptions and Patient summaries in the member states that have not yet launched these services;
- launching new services in all the member states (Original Clinical Documents, medical images, laboratory results, and discharge letters).

16 The Connecting Europe Facility (CEF) is a key EU funding instrument to promote growth, jobs and competitiveness through targeted infrastructure investment at European level.

6.4 Deployment

In March 2021, 7 member states have their services in routine operation. By 2023, the ePrescription and Patient Summary services will gradually be implemented in 24 participating countries.

The plan is that member states will commence operation of the new Original Clinical Document service in 2022 and 2023 with the new services for medical images, discharge letters, laboratory results and rare diseases.

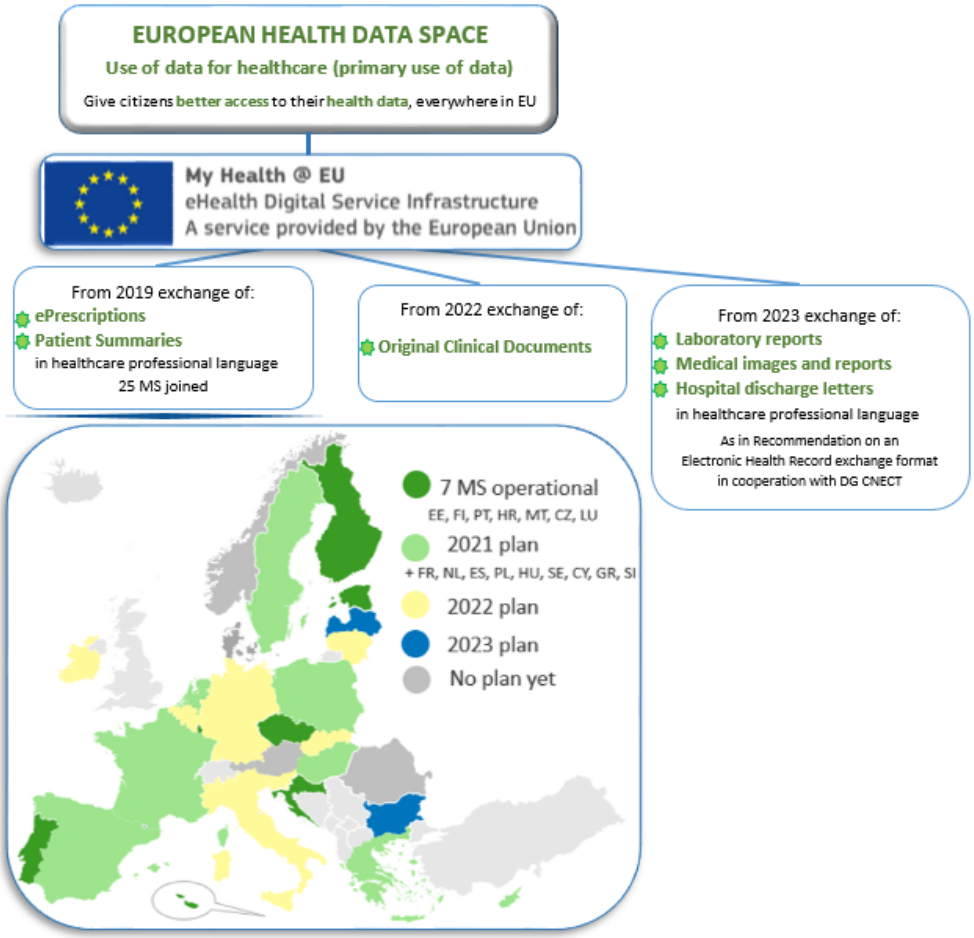

Figure 8 European Health Data Space

6.5 Conclusion

For many years, the focus has been on building the eHDSI infrastructure and implementing cross-border ePrescription and Patient Summary services. However, this will now soon be completed. Instead, the focus has shifted to plans for new services, which can use the same infrastructure and further build on existing services, i.e. Original Clinical Documents and the X-eHealth services for medical images, discharge letters, laboratory results and rare diseases.

The Covid-19 pandemic has emphasised the need for cross-border services and digital infrastructure. Examples of new services currently being developed are the Contact Tracing App to trace Covid-19 and the EU Digital Covid Certificate to facilitate the safe free movement within the EU during the pandemic.

Another area of focus is the secondary use of data, which will be investigated and worked on in EHDS2.

7. Plan for continued work in the Nordic and Baltic countries

7.1 Vision 2030

At the Nordic Council of Ministers´ meeting in mid-August 2019, the Nordic prime ministers agreed that cooperation will increasingly focus on climate and sustainable development. The Nordic Council of Ministers' new *Vision 2030* aims to make the Nordic Region the most sustainable and integrated region in the world.

By fully harnessing the potential of digitalisation, the Nordic countries can create the first genuinely integrated region in the world, serving as an encouraging example to others at EU level and globally. This goal also supports the objectives to develop digital systems in cooperation with partner countries, Nordic countries and Baltic countries. In addition to the economy, efforts can be made to enhance people's wellbeing and improve system safety.

7.2 Finnish Presidency of the Nordic Council of Ministers in 2021

Finland holds the Presidency of the Nordic Council of Ministers in 2021. The Presidency's key project is *Achieving the World's Smoothest Cross-Border Mobility and Daily Life Through Digitalisation*. It aims to create a common model and practices for improving and increasing cross-border data exchange effectiveness. The model will be developed during a three-year project 2021-2023, focusing on different life events and related key data and service packages. The life events are:

- Studies in other Nordic countries and the Baltics
- Use of health services in other Nordic countries and the Baltics
- The versatile use of the Nordic and Baltic legal databases

Within the life events, service and information packages relevant to everyday life and mobility have been selected for implementation. With regards to these, cross-border access to information and the exchange of information between authorities will be promoted. The starting point of the project is a person's everyday life, which includes as some of the selected key data and service packages, among other things, the need to use healthcare services, as well as data exchange supporting these services.

Digital solutions, data exchange and interoperability can support cross-border mobility. Enabling people to have cross-border daily lives will require many things, such as integrating digital services, common interface solutions, administrative coordination and cooperation, legislative reform and, in particular, the easy and interoperable exchange of data between countries.

Work toward this objective has already taken place in a range of projects, but a comprehensive vision and political support will provide the basis for the practical implementation of project outcomes. Nordic and Baltic countries as leading countries worldwide and as European leaders in digitalisation (EU DESI 2020), together with internationally unique cooperation with Estonia, are giving credibility to efforts to build political support and a common vision during the Presidency of the Nordic Council of Ministers.

7.3 Pilot projects

This report is the result of a subproject to *Healthcare and care through distance-spanning technologies (VOPD)*.

In the original project assignment, there was a goal to implement 2-3 pilot projects on ePrescriptions. That will, unfortunately, not be possible, since the necessary legislative updates will not be adopted in Sweden before the main project ends in June 2021.

However, the plan is to go live with the Nordic pilot projects for cross-border ePrescription services as soon as the necessary legislation updates have been adopted in Sweden.

The plan is to launch the services at a limited number of pharmacies in border areas and other important cross-border sites, for example, airports and harbours. Examples of areas could include:

- Helsinki (city and airport)
- Stockholm (city and airport)
- Uppsala
- Mariehamn (city and harbour)
- Haparanda – Finland and Sweden
- Övertorneå – Finland and Sweden
- (Tallinn)

VOPD is a priority project for 2018–2020 (extended to June 2021 due to the Covid-19 pandemic) forming part of the Swedish Presidency Programme of Nordic Council of Ministers 2018.

The Council of Ministers for Health (MR-Health) has initiated a follow-up project, *Healthcare and care through distance-spanning solutions in the light of the outbreak of COVID-19 (VOPD 2.0)*.

The work with cross-border ePrescriptions and Patient Summaries will continue in the new project under the Finnish Presidency described in the previous chapter.

7.4 Conclusion

In the Nordic countries, it is common to study, work or live in a neighbouring Nordic country. Many Nordic inhabitants travel to the rest of Europe, sometimes for more extended periods. For these people, cross-border services can facilitate life and provide extra security.

The Nordic Council of Ministers' Vision 2030 aims to make the Nordic Region the most sustainable and integrated region in the world.

Of the Nordic countries, Finland and Sweden have decided to implement cross-border ePrescription services. Finland has already done so. Sweden will technically be ready to go live in 2021 and will do so as soon as the necessary legislation updates have been adopted.

Only Finland has decided to implement cross-border Patient Summaries and plans to do so in 2023/2024.

In March 2021, Denmark, Iceland (EFTA) and Norway (EFTA), together with Austria and Romania, have not committed to establishing a National Contact Point for eHealth.

Looking at developments in the rest of Europe, 16 out of 27 EU countries plan, by 2023, to implement both cross-border ePrescription and Patient Summary services. Also, another two countries plan to introduce ePrescriptions and six are planning Patient Summaries. These countries will thereby be ready to implement the planned new services.

Therefore, the Health and Digital Europe Executive Agency will launch a call for grants in the autumn of 2021, where the aim will be to enlarge the geographic coverage and scope of MyHealth@EU (eHDSI).

The plan is that member states will commence operation of the new Original Clinical Document service in 2022 and 2023, with new services for medical images, discharge letters, laboratory results and rare diseases.

If the Nordic region is to become the most sustainable and integrated region in the world by 2030, all of the Nordic countries need to start working and connect to the European digital infrastructure and be part of MyHealth@EU (eHDSI) and the European Health Data Space. The time to act is now!